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21968	7590	10/08/2003	EXAMINER	
NEKTAR THERAPEUTICS			JOHNSON, EDWARD M	
150 INDUSTRIAL ROAD			ART UNIT	
SAN CARLOS, CA 94070			PAPER NUMBER	

1754

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/996,020

**Applicant(s)**

HANNA ET AL.

**Examiner**

Edward M. Johnson

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-123 is/are pending in the application.
- 4a) Of the above claim(s) 30-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-63, 70-80, 83-86, 90-109 and 113-123 is/are rejected.
- 7) ☒ Claim(s) 64-69, 81, 82, 87-89 and 110-112 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/765,540.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 45-123 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that it would not be a burden to examine both inventions. This is not found persuasive because Applicant does not appear to respond to the Examiner's specific showing of burden nor the reasoning behind restricting the two inventions, and also because examining 94 claims would be a burden even if there were only a single claimed invention, which Applicant does not even appear to allege.

The requirement is still deemed proper and is therefore made FINAL.

***Specification***

2. The disclosure is objected to because of the following informalities: the Brief Description of the Drawings is unlabeled. Examiner suggests inserting --Brief Description of the Drawings--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 45-56, 100-106 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45, line 3, "the flows" lacks antecedent basis.

Claim 100, line 6, "the flow" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 57-63, 70-80, 83-86, 90-109, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. US 4,514,574.

Regarding claims 57, 90, 100, and 107, Inoue '574 discloses supercritical gas extraction of isomers with carbon dioxide solvent (see abstract, Examples).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106, 108-109, and 113, Inoue '574 discloses two isomers, a solvent comprising carbon dioxide and polar solvents, contacting at the

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claimed conditions (see abstract, Examples, and column 2, lines 11-21).

7. Claims 57-63, 70-80, 83-86, 90-109, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebastian US 5,196,575.

Regarding claims 57, 90, 100, and 107, Sebastian '575 discloses supercritical separation of isomers comprising flowing supercritical carbon dioxide/polar solvent mixture, contacting the isomers, and precipitating (see column 2, lines 15-35).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106, 108-109, and 113, Sebastian '575 discloses two isomers and carbon dioxide/polar solvent solution with the claimed method steps and particular conditions (see column 2, lines 27-20, abstract, and Examples).

8. Claims 57-63, 70-80, 83-86, and 90-106 rejected under 35 U.S.C. 102(b) as being anticipated by Murthy et al. US 4,737,384.

Regarding claims 57, 90, and 100, Murthy '384 discloses depositing a coating onto a substrate comprising exposing a substrate at supercritical temperatures and pressures to a solution (see column 2, lines 11-24).

Regarding claims 58, 60-62, 70-79, 84-86, 95-99, and 102-106, Murthy '384 discloses a solution at supercritical

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temperatures and pressures (see column 2, line 16) and carbon dioxide and other solvents (see column 4, line 11).

Regarding claim 59, Murthy '384 discloses insoluble material dispersed in the solvent undissolved (see column 5, lines 1-15).

Regarding claims 63, 80, 83, 91-94, 101 Murthy '384 discloses exposing a substrate that is already present to a solution (see column 2, lines 15-17).

9. Claims 57-63, 70-80, and 90-106 rejected under 35 U.S.C. 102(b) as being anticipated by Cole et al. US 5,066,522.

Regarding claims 57, 90, and 100, Cole '522 discloses coating a substrate by admixing with a supercritical fluid and precursor adhesive composition (see abstract).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106 Cole '522 discloses mixing a supercritical fluid, which contains water (abstract), dispersion (see Figures and column 3, lines 10-13), carbon dioxide (see column 1, lines 18-25).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

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the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Inoue '574.

Regarding claims 114-123, Inoue '574 discloses supercritical gas extraction of isomers (see abstract, Examples).

12. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over anticipated Sebastian '575.

Regarding claims 114-123, Sebastian '575 discloses supercritical separation of isomers comprising flowing supercritical carbon dioxide/polar solvent mixture, contacting the isomers, and precipitating (see column 2, lines 15-35).

13. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over anticipated Murthy '384.

Regarding claims 114-123, Murthy '384 discloses depositing a coating onto a substrate comprising exposing a substrate at supercritical temperatures and pressures to a solution (see column 2, lines 11-24).

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14. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cole '522.

Regarding claims 114-123, Cole '522 discloses coating a substrate by admixing with a supercritical fluid and precursor adhesive composition (see abstract).

15. In the event any differences can be shown for the product of the product-by-process claims 114-123, as opposed to the product taught by Inoue, Sebastian, Murthy, and/or Cole, such differences would have been obvious to one of ordinary skill in the art at the time the invention was made as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (Fed.Cir. 1985).

***Allowable Subject Matter***

16. Claims 45-56 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

17. Claims 64-69, 81-82, 87-89, 110-112 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



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The following is a statement of reasons for the indication of allowable subject matter: It would not have been obvious to one of ordinary skill in the art at the time the invention was made to: 1. enter both flows at the same location and simultaneously extract the vehicle from the substance at the location in the method of the instant claim 45; 2. flow the supercritical fluid using the coaxial nozzle with passages that terminate adjacent to one another in the method of the instant claims 64-65 and 110-111; 3. use the 0.001-0.2 ratio of solution/suspension to supercritical fluid in the method of the instant claims 81 and 112; 4. use less than about 30% of first vehicle in the method of the instant claim 82; 5. use a seed of insoluble material in the second vehicle to induce nucleation upon contact in the method of the instant claim 87; nor 6. switch between two or more particle formation vessels or collecting means in the method of the instant claim 89;.

#### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tan et al. US 5,336,837 discloses a process for separating a mixture of isomers comprising extraction with supercritical carbon dioxide and propane (see abstract) elution, multiple stages, separating

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the absorbent particles and reducing the pressure (see abstract, Examples and column 4, lines 20-53).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M. Johnson whose telephone number is 703-305-0216. The examiner can normally be reached on M-F 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 703-308-3837. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

EMJ

  
**STEVEN BOS  
PRIMARY EXAMINER  
GROUP 1100**